REMARKS

Claims 1-18 and 31-45 were pending. With the present Amendment, the Applicants amend Claims 1, 18, 31, 33, and 34; therefore, Claims 1-18 and 31-45 remain pending for consideration. While the Applicants do not agree with or acquiesce to the claim rejections, the Applicants have amended the aforementioned claims in an effort to expedite prosecution. The Applicants reserve the right to pursue all previous versions of all amended claims in one or more future applications.

Claim Rejections Under 35 U.S.C. § 103

Claims 1-18 and 31-45 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,197,049 to Shaolian, et al. in view of U.S. Patent No. 6,379,382, to Yang. The Applicants respectfully traverse the rejection, as the Shaolian-Yang combination fails to teach, suggest, or otherwise render the claims obvious.

Claims 1-17

Claim 1 recites, among other things:

> 1. An endolumenal prosthesis . . . comprising:
> a tubular wire support . . . ; and
> a porous tubular ePTFE sheath on the wire support, the tubular sheath having a sheath proximal end region and a sheath distal end region, wherein the sheath is porous and configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath at the sheath proximal and distal end regions.

The applied art fails to teach, suggest, or otherwise render obvious, at least a prosthesis comprising a tubular wire support and *a porous* tubular ePTFE sheath *configured to inhibit sufficient cellular ingrowth* through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath at the sheath proximal and distal end regions.

Instead, Shaolian provides (emphasis added), "in a preferred embodiment of the invention, the material of sleeve 44 is sufficiently *porous to permit ingrowth* of endothelial cells . . ." and "in a central zone 57 of the prosthesis 42, the polymeric sleeve 44 may either be nonporous, or provided with pores of relatively lower porosity." Shaolian, col. 6, lines 41-43 and 65-67. Nowhere does Shaolian teach or suggest a porous ePTFE sheath that is also configured to

inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath at the sheath proximal and distal end regions.

Similarly, Yang fails to teach or suggest a porous ePTFE sheath that is also configured to inhibit sufficient cellular ingrowth through the wall of the sheath to permit the formation of a viable neointimal layer on the lumenal surface of the sheath at the sheath proximal and distal end regions. Therefore, even when combined, the Shaolian-Yang combination also fails to teach or suggest all the language of Claim 1. The applied art subsequently fails to render Claim 1 obvious.

In addition, Shaolian and Yang may not be combined because the combination renders Shaolian unsatisfactory for its intended purpose and because references cannot be combined where a reference teaches away from their combination. The M.P.E.P. clearly explains that a "proposed modification cannot render the prior art unsatisfactory for its intended purpose." M.P.E.P. § 2143.01(V). The M.P.E.P. also explains, "It is improper to combine references where the references teach away from their combination." M.P.E.P. § 2141.02, 2145(X)(D)(2).

Shaolian as a whole (and particularly column 6, lines 41-67) teaches *sleeves having sufficient porosity to permit tissue ingrowth* at least at the proximal and distal tissue-contacting portions. For example, Shaolian explains that at the proximal and distal portions of the prosthesis (the portions of the prosthesis that contact the vasculature), "the prosthesis preferably encourages endothelial growth, or, at least, permits endothelial growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage." Shaolian, column 6, lines 57-61.

Since Shaolian explicitly teaches the desirability of tissue ingrowth through an ePTFE structure in contact with vascular structure, such as at a sheath's proximal and distal end regions, it would be improper to modify such teachings to render it unsatisfactory for such intended purpose. The Office Action proposes to modify Shaolian in exactly this impermissible manner, which renders the combination improper.

For example, the Office Action admits "Shaolian fails to teach a specific embodiment in which the sheath is configured to inhibit sufficient cellular ingrowth at the proximal and distal end regions," (Office Action, page 3). However, the Office Action combines Shaolian with Yang

and concludes, "Therefore, it would have been obvious . . . to configure [] Shaolian's sheath such that it is also configured to inhibit sufficient cellular ingtowth through the proximal and distal end regions."

The Office Action appears to disregard the M.P.E.P. requirements provided above, namely that a "proposed modification cannot render the prior art unsatisfactory for its intended purpose" (M.P.E.P. § 2143.01) and that "It is improper to combine references where the references teach away from their combination" (M.P.E.P. §§ 2141.02, 2145).

Modifying Shaolian as proposed by the Office Action (e.g., by providing a sheath that inhibits cellular ingrowth) renders Shaolian unsatisfactory for its intended purpose (e.g., a prosthesis that encourages endothelial growth or at least permits such growth to infiltrate portions of the prosthesis in order to enhance anchoring and minimize leakage). In addition, by emphasizing the desirability of tissue ingrowth through an ePTFE structure in contact with vascular structure, such as at a sheath's proximal and distal end regions, Shaolian actually teaches away from the Office Action's proposed combination. Therefore, the Office Action has improperly combined the applied art. As a result, the Shaolian-Yang combination cannot render the claims obvious.

Claims 2-17 depend from Claim 1, and therefore distinguish over the applied art for at least the same reasons discussed above. In addition, Claims 2-17 distinguish over the applied art for the unique combinations of features recited in those claims.

For example, the applied art does not teach, suggest, or otherwise render obvious an ePTFE sheath having a wall thickness of no greater than about 0.2 mm (as required in Claim 2), a density of at least about 0.5 g/ml, 0.75 g/ml, or within the range of from about 1.1 to about 1.5 g/ml (as required in Claims 5-7, respectively), an average distance between ePTFE nodes within a range of from about 6 microns to about 80 microns (as required in Claims 8-10), or having a water entry pressure in the range of from about 10 psi to about 24 psi (as required in Claim 17). Therefore, Claims 2, 5-7, and 17 distinguish over the applied art for at least these additional reasons, as well.

The Office Action dismisses the language of these claims as merely optimum or workable ranges involving only routine skill in the art. See Office Action, pages 3-4. However, the Board of Patent Appeals and Interferences recently rejected similar conclusions in a similar situation.

In Ex parte Whalen II (decided July 23, 2008), the Board explained (emphasis added), "While 'the discovery of an optimum value of a variable in a known process is normally obvious,' this is not always the case. *One exception to the rule is where the parameter optimized was not recognized in the prior art as one that would affect the results.*" Whalen II, p. 14 (citing In re Antoine, 559 F.2d 618, 620 (C.C.P.A. 1977)).

The Board also explained, "Here, the Examiner has not pointed to any teaching in the cited references, or provided any explanation based on scientific reasoning, that would support the conclusion that those skilled in the art would have considered it obvious to 'optimize' the prior art compositions by increasing their viscosity to the level recited in the claims." Id. Therefore, the Board concluded that the Examiner had not made out a prima facie case of obviousness.

The Office Action in the present Application similarly fails to provide any indication that the language of Claims 2, 5-7, and 17 are merely optimized values of parameters that have been recognized in the prior art as parameters that would affect results. Therefore, for the same reasons discussed in Whalen II, the present Office Action also fails to establish a prima facie case of obviousness of Claims 2, 5-7, and 17.

Claim 18

Claim 18 recites, among other things:

> 18. A bifurcated endolumenal prosthesis . . . comprising:
> a proximal wire support section . . . ;
> a first wire branch section at the distal end of the proximal support;
> a second wire branch section at the distal end of the proximal support; and
> a porous membrane carried by the wire support section, the membrane having a membrane proximal end region and membrane distal end regions and configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and distal end regions.

For similar reasons as those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a prosthesis comprising a porous membrane configured to inhibit cellular growth through the membrane sufficient to enable the formation of a thin, viable neointimal layer on the lumenal surface of the membrane at least at the membrane proximal and

distal end regions. In addition, as discussed above, the Office Action impermissibly combines the applied art.

Therefore, for at least these reasons, Claim 18 distinguishes over the applied art, as well.

Claim 31

Claim 31 recites:

> 31. A prosthetic vascular graft, comprising:
> an expandable tubular wire support;
> a porous, tubular ePTFE layer carried by the support, the ePTFE layer having:
> a wall thickness of less than about 0.15 millimeters;
> an average density of greater than about 0.75 grams per milliliter; and
> an average distance between nodes in the range of between about 6 to about 80 microns;
> so that the porous ePTFE layer prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length, which are in contact with a vessel wall.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a graft comprising a porous, ePTFE layer that prevents the formation and nourishment of a viable neointimal layer therethrough along portions of the tubular ePTFE layer's axial length, which are in contact with a vessel wall. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 31 relating to wall thickness, average density, and average distance between nodes as merely optimized parameters. The Office Action fails to establish a prima facie case of obviousness of Claim 31 at least because it fails to indicate where the allegedly optimized parameters were recognized in the prior art as parameters that would affect results.

Therefore, for at least these reasons, Claim 31 distinguishes over the applied art, as well.

Claim 32

Claim 32 recites, among other things:

> 32. An artificial vascular prosthesis comprising an enlargeable support structure having an expanded, porous, polytetrafluoroethylene layer thereon, the layer having a microstructure consisting of nodes interconnected by fibrils which prevents tissue ingrowth through portions of the layer that contact a vessel wall

when the prosthesis is implanted to span an aneurysm, in which either the density is greater than about 1 gram per milliliter or the wall thickness is less than about 0.2 millimeters, or both.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a prosthesis comprising an expanded, porous, polytetrafluoroethylene layer which prevents tissue ingrowth through portions of the layer that contact a vessel wall when the prosthesis is implanted to span an aneurysm. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 32 relating to density and wall thickness as merely optimized parameters. The Office Action fails to establish a prima facie case of obviousness of Claim 32 at least because it fails to indicate where the allegedly optimized parameters were recognized in the prior art as parameters that would affect results.

Therefore, for at least these reasons, Claim 32 distinguishes over the applied art, as well.

Claim 33

Claim 33 recites, among other things:

33. A method of treating a patient, comprising:
providing an implantable tubular prosthesis, having a porous ePTFE layer thereon . . . ;
positioning the prosthesis across a defect . . . ; and
inhibiting formation of a viable neointima on a second side of the layer throughout the contacting portion, nourished through the layer;
wherein the inhibiting step comprises providing the ePTFE layer with a density of greater than about 0.75 grams per milliliter and a wall thickness of less than 0.2 mm.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a method of treating a patient comprising providing prosthesis having a porous ePTFE layer thereon and inhibiting the formation of a viable neointimal on a second side of the layer throughout the contacting portion, nourished through the layer. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 33 relating to density and wall thickness as merely optimized parameters. The Office Action fails to establish a prima facie case of obviousness of Claim 33 at least because it fails to indicate where the

allegedly optimized parameters were recognized in the prior art as parameters that would affect results.

Therefore, for at least these reasons, Claim 33 distinguishes over the applied art, as well.

Claims 34-45

Claim 34 has been amended to recite, among other things:

> 34. An endolumenal prosthesis . . . comprising:
> a tubular wire support . . .; and
> a porous, tubular ePTFE sheath on the wire support, the porous, tubular sheath having a proximal end and a distal end and being configured to have a water entry pressure of at least about 10 psi, and wherein the porous tubular sheath is configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath.

For similar reasons to those discussed above, the applied art fails to teach, suggest, or otherwise render obvious a prosthesis comprising a porous, tubular ePTFE sheath on a wire support configured to inhibit the formation of a viable neointimal layer on the lumenal surface of the sheath through the wall of the sheath. In addition, as discussed above, the Office Action impermissibly combines the applied art. Furthermore, the Office Action impermissibly dismisses the additional requirements of Claim 34 relating to water entry pressure as merely an optimized parameter. The Office Action fails to establish a prima facie case of obviousness of Claim 34 at least because it fails to indicate where the allegedly optimized parameter was recognized in the prior art as a parameter that would affect results.

Therefore, for at least these reasons, Claim 34 distinguishes over the applied art, as well. Claims 35-45 depend from Claim 34, and therefore distinguish over the applied art for at least the same reasons. In addition, Claims 35-45 distinguish over the applied art for the unique combinations of features recited in those claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this

application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

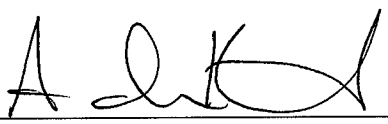
In view of the foregoing amendments and remarks, the Applicants submit that this application is in condition for allowance and such action is respectfully requested. If any issues remain or require further clarification the Examiner is respectfully requested to call the Applicants' counsel at the number indicated below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 16, 2009

By: 

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